

Andrew J. Miller  
Louis H. Weinstein  
BUDD LARNER, P.C.  
150 John F. Kennedy Parkway  
Short Hills, NJ 07078  
(973) 379-4800

*Attorneys for Defendants  
Dr. Reddy's Laboratories, Inc. and  
Dr. Reddy's Laboratories, Ltd.*

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

SUCAMPO AG, SUCAMPO PHARMA-  
CEUTICALS, INC., R-TECH UENO, LTD.,  
TAKEDA PHARMACEUTICAL COMPANY  
LIMITED, TAKEDA PHARMACEUTICALS  
USA, INC. and TAKEDA PHARMA-  
CEUTICALS AMERICA, INC.,

Plaintiffs,

v.

DR. REDDY'S LABORATORIES, INC., and  
DR. REDDY'S LABORATORIES, LTD.,

Defendants.

Civil Action No. 3:14-cv-07114-MAS-DEA

*Document Electronically Filed*

**ANSWER AND COUNTERCLAIMS OF DR. REDDY'S  
LABORATORIES, INC. AND DR. REDDY'S LABORATORIES, LTD.**

Defendants, Dr. Reddy's Laboratories Inc. ("DRL Inc.") and Dr. Reddy's Laboratories, Ltd. ("DRL Ltd.") (collectively "DRL"), by their attorneys, answer Plaintiffs' Sucampo AG, Sucampo Pharmaceuticals, Inc., R-Tech Ueno, Ltd., Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals USA, Inc. and Takeda Pharmaceuticals America, Inc.'s ("Sucampo's" or "Plaintiffs'") Complaint For Patent Infringement ("Complaint") as follows:

**THE PARTIES**

1. DRL is without sufficient knowledge to admit or deny the allegations of Paragraph 1 of the Complaint.

2. DRL is without sufficient knowledge to admit or deny the allegations of Paragraph 2 of the Complaint.

3. DRL is without sufficient knowledge to admit or deny the allegations of Paragraph 3 of the Complaint.

4. DRL is without sufficient knowledge to admit or deny the allegations of Paragraph 4 of the Complaint.

5. DRL is without sufficient knowledge to admit or deny the allegations of Paragraph 5 of the Complaint.

6. DRL is without sufficient knowledge to admit or deny the allegations of Paragraph 6 of the Complaint.

7. DRL admits DRL Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 107 College Road East, Princeton, New Jersey 08540 and is a wholly-owned subsidiary of DRL Ltd. DRL admits DRL Inc. is registered to do business in New Jersey and does business in this Judicial District. DRL admits that DRL Inc. has acted from time to time as an agent of DRL Ltd. DRL denies the remaining allegations of Paragraph 7 of the Complaint.

8. DRL Inc. does not contest personal jurisdiction with respect to this action in this Court.

9. Admitted.

10. DRL Ltd. does not contest personal jurisdiction with respect to this action in this Court.

11. DRL Inc. and DRL Ltd. do not contest jurisdiction with respect to this action in this Court.

### **JURISDICTION AND VENUE**

12. DRL admits this is a civil action alleging infringement of United States Patents 6,414,016, 8,071,613, 7,795,312, 8,097,653, 8,389,542, 8,026,393, and 8,338,639 (collectively, “the patents-in-suit”). DRL admits that this action arises under the patent laws of the United States, 35 U.S.C. § 100 *et seq.* DRL denies the remaining allegations of Paragraph 12 of the Complaint.

13. Admitted.

14. Admitted.

15. DRL does not contest personal jurisdiction or venue. DRL admits it sent a letter to Plaintiffs dated October 1, 2014 (“DRL Notice Letter”) and that such letter speaks for itself. DRL denies the remaining allegations of Paragraph 15 of the Complaint.

16. DRL does not contest personal jurisdiction. DRL Inc. admits it is a corporation organized and existing under the laws of the State of New Jersey and that DRL Inc. has its principal place of business in the State of New Jersey, and is registered to do business and does business in the State of New Jersey. DRL need not respond to the conclusions of law contained in Paragraph 16 of the Complaint. To the extent a response is required, DRL denies the remaining allegations of Paragraph 16 of the Complaint.

**THE PATENTS-IN-SUIT**

17. DRL is without sufficient knowledge to admit or deny the allegations of Paragraph 17 of the Complaint.

18. DRL admits that with respect to NDA No. 021908 the US FDA has at certain times approved certain drug products for certain indications as stated in those approvals. DRL is without sufficient knowledge to admit or deny any further allegations of Paragraph 18 of the Complaint.

19. DRL is without sufficient knowledge to admit or deny the allegations of Paragraph 19 of the Complaint.

20. DRL is without sufficient knowledge to admit or deny the allegations of Paragraph 20 of the Complaint.

21. DRL is without sufficient knowledge to admit or deny that Sucampo AG owns United States Patent No. 6,414,016 (“the ‘016 patent”) titled “Anti-Constipation Composition.” DRL admits that a copy of the ‘016 patent is attached to the Complaint as Exhibit A. DRL admits that the ‘016 patent issued on July 2, 2002. DRL denies the remaining allegations of Paragraph 21 of the Complaint.

22. DRL is without sufficient knowledge to admit or deny the allegations of Paragraph 22 of the Complaint.

23. DRL is without sufficient knowledge to admit or deny that Sucampo AG owns United States Patent No. 8,071,613 (“the ‘016 patent”) titled “Anti-Constipation Composition.” DRL admits that a copy of the ‘613 patent is attached to the Complaint as Exhibit B. DRL admits that the ‘613 patent issued on December 6, 2011. DRL denies the remaining allegations of Paragraph 23 of the Complaint.

24. DRL is without sufficient knowledge to admit or deny the allegations of Paragraph 24 of the Complaint.

25. DRL is without sufficient knowledge to admit or deny that Sucampo AG owns United States Patent No. 7,795,312 (“the ‘312 patent”) titled “Method for Treating Abdominal discomfort.” DRL admits that a copy of the ‘312 patent is attached to the Complaint as Exhibit C. DRL admits the ‘312 patent issued on September 14, 2010. DRL denies the remaining allegations of Paragraph 25 of the Complaint.

26. DRL is without sufficient knowledge to admit or deny the allegations of Paragraph 26 of the Complaint.

27. DRL is without sufficient knowledge to admit or deny that Sucampo AG owns United States Patent No. 8,097,653 (“the ‘653 patent”) titled “Dosage Unit Comprising a Prostaglandin Analog for Treating Constipation.” DRL admits that a copy of the ‘653 patent is attached to the Complaint as Exhibit D. DRL admits the ‘653 patent issued on January 17, 2012. DRL denies the remaining allegations of Paragraph 27 of the Complaint.

28. DRL is without sufficient knowledge to admit or deny the allegations of Paragraph 28 of the Complaint.

29. DRL is without sufficient knowledge to admit or deny that Sucampo AG owns United States Patent No. 8,389,542 (“the ‘542 patent”) titled “Dosage Unit Comprising a Prostaglandin Analog for Treating Constipation.” DRL admits that a copy of the ‘542 patent is attached to the Complaint as Exhibit E. DRL admits the ‘542 patent issued on March 5, 2013. DRL denies the remaining allegations of Paragraph 29 of the Complaint.

30. DRL is without sufficient knowledge to admit or deny the allegations of Paragraph 30 of the Complaint.

31. DRL is without sufficient knowledge to admit or deny that Sucampo AG and R-Tech Ueno, Ltd. co-own United States Patent No. 8,026,393 (“the ‘393 patent”) titled “Soft-Gelatin Formulation.” DRL admits that a copy of the ‘393 patent is attached to the Complaint as Exhibit F. DRL admits the ‘393 patent issued on September 27, 2011. DRL denies the remaining allegations of Paragraph 31 of the Complaint.

32. DRL is without sufficient knowledge to admit or deny the allegations of Paragraph 32 of the Complaint.

33. DRL is without sufficient knowledge to admit or deny that Sucampo AG and R-Tech Ueno, Ltd. co-own United States Patent No. 8,338,639 (“the ‘639 patent”) titled “Soft-Gelatin Formulation.” DRL admits that a copy of the ‘639 patent is attached to the Complaint as Exhibit G. DRL admits the ‘639 patent issued on December 25, 2012. DRL denies the remaining allegations of Paragraph 33 of the Complaint.

34. DRL is without sufficient knowledge to admit or deny the allegations of Paragraph 34 of the Complaint.

35. DRL is without sufficient knowledge to admit or deny the allegations of Paragraph 35 of the Complaint.

36. DRL admits that certain of the patents-in-suit are listed for certain strengths of AMITIZA<sup>®</sup>. DRL denies the remaining allegations of Paragraph 36 of the Complaint.

**DRL’S ANDA AND NOTICE LETTER**

37. DRL admits that DRL prepared and submitted Abbreviated New Drug Application No. 206994 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) to obtain approval for the activities stated therein that required FDA approval and included a certification with respect to the patents-in-suit under §

505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355) (“Paragraph IV Certification”) that speaks for itself. DRL denies the remaining allegations of Paragraph 37 of the Complaint.

38. DRL admits that DRL sent the DRL Notice Letter to Plaintiffs on October 1, 2014 and that such letter speaks for itself. DRL is without sufficient knowledge to admit or deny that Plaintiffs first received the Notice Letter on October 3, 2014. DRL denies the remaining allegations of Paragraph 38 of the Complaint.

39. DRL is without sufficient knowledge to admit or deny the allegations of Paragraph 39 of the Complaint.

40. Admitted.

41. DRL admits that the dosage form of its proposed ANDA products is a soft gelatin capsule for oral administration. DRL denies the remaining allegations of Paragraph 41 of the Complaint.

42. DRL admits that the capsule fill for DRL’s ANDA Products comprises lubiprostone and medium chain fatty acid triglycerides. DRL denies the remaining allegations of Paragraph 42 of the Complaint.

43. Admitted.

44. Admitted.

45. Admitted.

46. Admitted.

47. Admitted.

48. DRL admits that the following is stated in one or more of the Factual and Legal Basis Memoranda included with the DRL Notice Letter: “The ‘016 patent reports that the mono-

cyclic to bi-cyclic tautomer ratio of lubiprostone in  $\text{CDCl}_3$  is 1:24 ('4:96')." Further answering, DRL states that the Factual and Legal Basis Memoranda included with the DRL Notice Letter speak for themselves and respectfully refers the Court to the Factual and Legal Basis Memoranda included with the DRL Notice Letter for their contents.

49. DRL admits that the following is stated in one or more of the Factual and Legal Basis Memoranda included with the DRL Notice Letter: "The '016 patent reports that the mono-cyclic to bi-cyclic tautomer ratio of lubiprostone in  $\text{CDCl}_3$  is 1:24 ('4:96')." Further answering, DRL states that the Factual and Legal Basis Memoranda included with the DRL Notice Letter speak for themselves and respectfully refers the Court to the Factual and Legal Basis Memoranda included with the DRL Notice Letter for their contents.

50. DRL admits that the following is stated in one or more of the Factual and Legal Basis Memoranda included with the DRL Notice Letter: "The '016 patent reports that the mono-cyclic to bi-cyclic tautomer ratio of lubiprostone in  $\text{CDCl}_3$  is 1:24 ('4:96')." Further answering, DRL states that the Factual and Legal Basis Memoranda included with the DRL Notice Letter speak for themselves and respectfully refers the Court to the Factual and Legal Basis Memoranda included with the DRL Notice Letter for their contents.

51. DRL admits that it seeks approval for the 8 mcg ANDA product for the indication sought for that product in DRL's ANDA and that DRL's ANDA speaks for itself and respectfully refers the court to DRL's ANDA for its contents.

52. Admitted.

53. The allegations of Paragraph 53 of the Complaint are legal conclusions to which no response is required. To the extent a response is required the allegations are denied.



54. The allegations of Paragraph 54 of the Complaint are legal conclusions to which no response is required. To the extent a response is required the allegations are denied.

55. The DRL Notice Letter is a document that speaks for itself and DRL respectfully refers the Court to that document for its contents. The DRL Notice Letter was sent with Factual and Legal Basis Memoranda that speak for themselves, and DRL respectfully refers the Court to those documents for their contents.

56. The DRL Notice Letter is a document that speaks for itself and DRL respectfully refers the Court to that document for its contents. The DRL Notice Letter was sent with Factual and Legal Basis Memoranda that speak for themselves, and DRL respectfully refers the Court to those documents for their contents.

57. The allegations of Paragraph 57 of the Complaint are legal conclusions to which no response is required. To the extent a response is required the allegations are denied.

58. The allegations of Paragraph 58 of the Complaint are legal conclusions to which no response is required. To the extent a response is required the allegations are denied.

59. The DRL Notice Letter is a document that speaks for itself and DRL respectfully refers the Court to that document for its contents. The DRL Notice Letter was sent with Factual and Legal Basis Memoranda that speak for themselves, and DRL respectfully refers the Court to those documents for their contents.

60. The allegations of Paragraph 60 of the Complaint are legal conclusions to which no response is required. To the extent a response is required the allegations are denied.

61. The allegations of Paragraph 61 of the Complaint are legal conclusions to which no response is required. To the extent a response is required the allegations are denied.

62. The DRL Notice Letter is a document that speaks for itself and DRL respectfully refers the Court to that document for its contents. The DRL Notice Letter was sent with Factual and Legal Basis Memoranda that speak for themselves, and DRL respectfully refers the Court to those documents for their contents.

63. The allegations of Paragraph 63 of the Complaint are legal conclusions to which no response is required. To the extent a response is required the allegations are denied.

64. The DRL Notice Letter is a document that speaks for itself and DRL respectfully refers the Court to that document for its contents. The DRL Notice Letter was sent with Factual and Legal Basis Memoranda that speak for themselves, and DRL respectfully refers the Court to those documents for their contents.

65. The allegations of Paragraph 65 of the Complaint are legal conclusions to which no response is required. To the extent a response is required the allegations are denied.

66. The DRL Notice Letter is a document that speaks for itself and DRL respectfully refers the Court to that document for its contents. The DRL Notice Letter was sent with Factual and Legal Basis Memoranda that speak for themselves, and DRL respectfully refers the Court to those documents for their contents.

67. The allegations of Paragraph 67 of the Complaint are legal conclusions to which no response is required. To the extent a response is required the allegations are denied.

68. The allegations of Paragraph 68 of the Complaint are legal conclusions to which no response is required. To the extent a response is required the allegations are denied.

69. The allegations of Paragraph 69 of the Complaint are legal conclusions to which no response is required. To the extent a response is required the allegations are denied.

70. The DRL Notice Letter is a document that speaks for itself and DRL respectfully refers the Court to that document for its contents. The DRL Notice Letter was sent with Factual and Legal Basis Memoranda that speak for themselves, and DRL respectfully refers the Court to those documents for their contents.

71. The DRL Notice Letter is a document that speaks for itself and DRL respectfully refers the Court to that document for its contents. The DRL Notice Letter was sent with Factual and Legal Basis Memoranda that speak for themselves, and DRL respectfully refers the Court to those documents for their contents.

72. The allegations of Paragraph 72 of the Complaint are legal conclusions to which no response is required. To the extent a response is required the allegations are denied.

73. The allegations of Paragraph 73 of the Complaint are legal conclusions to which no response is required. To the extent a response is required the allegations are denied.

74. The DRL Notice Letter is a document that speaks for itself and DRL respectfully refers the Court to that document for its contents. The DRL Notice Letter was sent with Factual and Legal Basis Memoranda that speak for themselves, and DRL respectfully refers the Court to those documents for their contents.

75. The DRL Notice Letter is a document that speaks for itself and DRL respectfully refers the Court to that document for its contents. The DRL Notice Letter was sent with Factual and Legal Basis Memoranda that speak for themselves, and DRL respectfully refers the Court to those documents for their contents.

**DRL'S CHRONIC CONSTIPATION STUDY**

76. Admitted.

77. DRL's ANDA is a document that speaks for itself and it reports what was conducted and the matters that were evaluated. DRL respectfully refers the Court to DRL's ANDA for its contents.

78. DRL's ANDA is a document that speaks for itself and it reports what was conducted and the matters that were evaluated. DRL respectfully refers the Court to DRL's ANDA for its contents.

79. DRL's ANDA is a document that speaks for itself and it reports what was conducted and the matters that were evaluated. DRL respectfully refers the Court to DRL's ANDA for its contents.

80. DRL's ANDA is a document that speaks for itself and it reports what was conducted and the matters that were evaluated. DRL respectfully refers the Court to DRL's ANDA for its contents.

**DELAWARE ACTION MARKMAN ORDER**

81. Admitted that one or more employees of DRL Inc. and/or DRL Ltd. were aware of the recited action prior to October 1, 2014. DRL denies the remaining allegations of Paragraph 81 of the Complaint.

82. Admitted that said Order was filed in the Delaware District Court on or about said date and that said Order speaks for itself. DRL denies the remaining allegations of Paragraph 82 of the Complaint.

83. DRL is unable to form a belief as to whether one or more employees of DRL Inc. and/or DRL Ltd. were aware of said Order prior to October 1, 2014. DRL denies the remaining allegations of Paragraph 83 of the Complaint.

84. DRL answers that said Order speaks for itself and DRL denies the remaining allegations of Paragraph 84 of the Complaint.

85. DRL answers that said Order speaks for itself and DRL denies the remaining allegations of Paragraph 85 of the Complaint.

**DRL'S ALLEGED NOTICE LETTER DEFENSES**

86. DRL answers that the DRL Notice Letter and the Factual and Legal Basis Memoranda included with the DRL Notice Letter are documents that speak for themselves. DRL denies the remaining allegations of Paragraph 86 of the Complaint.

87. DRL answers that the DRL Notice Letter and the Factual and Legal Basis Memoranda included with the DRL Notice Letter are documents that speak for themselves. DRL denies the remaining allegations of Paragraph 87 of the Complaint.

88. DRL answers that the DRL Notice Letter and the Factual and Legal Basis Memoranda included with the DRL Notice Letter are documents that speak for themselves. DRL denies the remaining allegations of Paragraph 88 of the Complaint.

89. DRL answers that said patent is a document that speaks for itself. DRL denies the remaining allegations of Paragraph 89 of the Complaint.

90. DRL answers that said patent is a document that speaks for itself. DRL denies the remaining allegations of Paragraph 90 of the Complaint.

91. Admitted.

92. Admitted.

93. DRL answers that said patent is a document that speaks for itself. DRL denies the remaining allegations of Paragraph 93 of the Complaint.

94. DRL answers that said patent is a document that speaks for itself. DRL denies the remaining allegations of Paragraph 94 of the Complaint.

95. Admitted.

96. Admitted.

97. DRL answers that said patent is a document that speaks for itself. DRL denies the remaining allegations of Paragraph 97 of the Complaint.

98. DRL answers that said patent is a document that speaks for itself. DRL denies the remaining allegations of Paragraph 98 of the Complaint.

99. DRL answers that said patent is a document that speaks for itself. DRL denies the remaining allegations of Paragraph 99 of the Complaint.

100. DRL answers that said patent is a document that speaks for itself. DRL denies the remaining allegations of Paragraph 100 of the Complaint.

101. DRL answers that said patent is a document that speaks for itself. DRL denies the remaining allegations of Paragraph 101 of the Complaint.

102. DRL answers that the DRL Notice Letter and the Factual and Legal Basis Memoranda included with the DRL Notice Letter are documents that speak for themselves. DRL denies the remaining allegations of Paragraph 102 of the Complaint.

103. DRL answers that said patent is a document that speaks for itself. DRL denies the remaining allegations of Paragraph 103 of the Complaint.

104. Admitted.

105. DRL answers that said patent is a document that speaks for itself. DRL denies the remaining allegations of Paragraph 105 of the Complaint.

106. DRL answers that said patent is a document that speaks for itself. DRL denies the remaining allegations of Paragraph 106 of the Complaint.

107. DRL answers that said reference is a document that speaks for itself. DRL denies the remaining allegations of Paragraph 107 of the Complaint.

108. DRL answers that said reference is a document that speaks for itself. DRL denies the remaining allegations of Paragraph 108 of the Complaint.

109. DRL answers that said reference is a document that speaks for itself. DRL denies the remaining allegations of Paragraph 109 of the Complaint.

110. DRL answers that the prosecution history of said application speaks for itself. DRL denies the remaining allegations of Paragraph 110 of the Complaint.

111. DRL answers that the DRL Notice Letter and the Factual and Legal Basis Memoranda included with the DRL Notice Letter are documents that speak for themselves. DRL denies the remaining allegations of Paragraph 111 of the Complaint.

112. DRL answers that the DRL Notice Letter and the Factual and Legal Basis Memoranda included with the DRL Notice Letter are documents that speak for themselves. DRL denies the remaining allegations of Paragraph 112 of the Complaint.

113. DRL answers that said patent is a document that speaks for itself. DRL denies the remaining allegations of Paragraph 113 of the Complaint.

114. Admitted.

115. Admitted.

116. DRL answers that said patent is a document that speaks for itself. DRL denies the remaining allegations of Paragraph 116 of the Complaint.

117. Admitted.

118. Admitted.

119. DRL answers that said reference is a document that speaks for itself. DRL denies the remaining allegations of Paragraph 119 of the Complaint.

120. DRL answers that said reference is a document that speaks for itself. DRL denies the remaining allegations of Paragraph 120 of the Complaint.

121. Admitted.

122. Admitted.

123. DRL answers that said reference is a document that speaks for itself. DRL denies the remaining allegations of Paragraph 123 of the Complaint.

124. DRL answers that said reference is a document that speaks for itself. DRL denies the remaining allegations of Paragraph 124 of the Complaint.

125. DRL answers that the DRL Notice Letter and the Factual and Legal Basis Memoranda included with the DRL Notice Letter are documents that speak for themselves. DRL denies the remaining allegations of Paragraph 125 of the Complaint.

126. DRL answers that the DRL Notice Letter and the Factual and Legal Basis Memoranda included with the DRL Notice Letter are documents that speak for themselves. DRL denies the remaining allegations of Paragraph 126 of the Complaint.

127. DRL answers that said reference is a document that speaks for itself. DRL denies the remaining allegations of Paragraph 127 of the Complaint.

128. Admitted.

129. Admitted.

130. DRL answers that said patent is a document that speaks for itself. DRL denies the remaining allegations of Paragraph 130 of the Complaint.



131. DRL answers that said patent is a document that speaks for itself. DRL denies the remaining allegations of Paragraph 131 of the Complaint.

132. Admitted.

133. Admitted.

134. DRL answers that said reference is a document that speaks for itself. DRL denies the remaining allegations of Paragraph 134 of the Complaint.

135. DRL answers that said reference is a document that speaks for itself. DRL denies the remaining allegations of Paragraph 135 of the Complaint.

136. DRL answers that said reference is a document that speaks for itself. DRL denies the remaining allegations of Paragraph 136 of the Complaint.

**DRL'S ALLEGED INFRINGEMENT OF THE PATENTS-IN-SUIT**

137. DRL repeats and realleges paragraphs 1-136 as if fully set forth herein.

138. DRL admits it filed an ANDA sufficient to confer subject matter jurisdiction in this action under 35 U.S.C. § 271(e)(2)(A). DRL denies the remaining allegations of Paragraph 138 of the Complaint.

139. Denied.

140. Denied.

141. Denied.

142. Denied.

143. Denied.

**ANSWER TO PRAYER FOR RELIEF**

DRL denies that Plaintiffs are entitled to the judgment or any other relief prayed for in Paragraphs A-E of the Complaint.

## **DEFENSES**

### **First Defense**

Plaintiffs fail to state a claim upon which relief can be granted.

### **Second Defense**

The claims of the patents-in-suit, United States Patents 6,414,016, 8,071,613, 7,795,312, 8,097,653, 8,389,542, 8,026,393, and 8,338,639, are invalid for failing to satisfy one or more conditions of patentability set forth in Title 35, United States Code, including without limitation, §§ 101, 102, 103 and/or 112, and/or for non-statutory (obviousness-type) double patenting.

### **Third Defense**

DRL has not infringed, induced infringement or contributed to the infringement, and DRL will not infringe, induce infringement or contribute to the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable claim of the patents-in-suit, United States Patents 6,414,016, 8,071,613, 7,795,312, 8,097,653, 8,389,542, 8,026,393, and 8,338,639.

### **Fourth Defense**

Plaintiffs may not seek injunctive relief against DRL because Plaintiffs alleged damages are not immediate or irreparable, and Plaintiffs therefore have an adequate remedy at law.

## **COUNTERCLAIMS**

Counterclaim Plaintiffs Dr. Reddy's Laboratories, Inc. ("DRL Inc.") and Dr. Reddy's Laboratories, Ltd. ("DRL Ltd.") (collectively, "DRL" or "Counterclaim Plaintiffs"), for their Counterclaims against Counterclaim Defendants Sucampo AG, Sucampo Pharmaceuticals, Inc., R-Tech Ueno, Ltd., Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals USA,

Inc. and Takeda Pharmaceuticals America, Inc.'s (collectively "Sucampo" or "Counterclaim Defendants"), allege and aver as follows:

**THE PARTIES**

1. Counterclaim Plaintiff DRL Inc. is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 107 College Road East, Princeton, New Jersey 08540. DRL Inc. is a subsidiary of DRL Ltd.

2. Counterclaim Plaintiff DRL Ltd. is an Indian public limited liability company incorporated and existing under the laws of India and having a principal place of business at 7-1-27, Ameerpet, Hyderabad 500 016, Andhra Pradesh, India.

3. On information and belief, Counterclaim Defendant Sucampo AG is a Swiss corporation, having a primary place of business at Baarerstrasse 22, CH-6300, Zug, Switzerland.

4. On information and belief, Counterclaim Defendant Sucampo Pharmaceuticals, Inc. is a corporation having a principal place of business at 4520 East-West Highway, 3rd Floor, Bethesda, Maryland 20814.

5. On information and belief, Counterclaim Defendant R-Tech Ueno, Ltd. is a Japanese corporation having a principal place of business at NBF Hibiya Bldg., 10F, 1-1-7 Uchisaiwaicho, Chiyoda-ku, Tokyo 100-0011, Japan.

6. On information and belief, Counterclaim Defendant Takeda Pharmaceutical Company Limited is a Japanese corporation having a principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645, Japan.

7. On information and belief, Counterclaim Defendant Takeda Pharmaceuticals USA, Inc. is a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

8. On information and belief, Counterclaim Defendant Takeda Pharmaceuticals America, Inc. is a wholly-owned subsidiary of Takeda Pharmaceuticals USA, Inc., having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

### **JURISDICTION AND VENUE**

9. This is an action for a declaratory judgment, together with such further relief based thereon as may be necessary or proper, pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. The basis for a declaratory judgment is, as fully appears below, an actual controversy regarding United States Patents 6,414,016, 8,071,613, 7,795,312, 8,097,653, 8,389,542, 8,026,393, and 8,338,639 (the “patents-in-suit”) between Counterclaim Plaintiffs and Counterclaim Defendants arising under the United States Patent Laws, Title 35 of the United States Code.

10. This Court has subject matter jurisdiction over the action based on 28 U.S.C. §§ 1331 and 1338.

11. This Court has personal jurisdiction over Counterclaim Defendants at least because Counterclaim Defendants voluntarily filed, in this Court, the Complaint to which these Counterclaims are directed.

12. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400.

### **FACTUAL BACKGROUND**

13. DRL hereby incorporates Paragraphs 1-143 of its Answer and Paragraphs 1-12 of its Counterclaims as if expressly stated herein.

14. On information and belief, Plaintiff Sucampo Pharmaceuticals, Inc. holds approved New Drug Application (“NDA”) No. 021908, under which the FDA granted approval

on January 31, 2006 for 24 mcg lubiprostone capsules and on April 29, 2008 for 8 mcg lubiprostone capsules, both marketed in the United States under the trade name AMITIZA®.

15. On information and belief, Sucampo AG owns United States Patent No. 6,414,016 (“the ‘016 patent”), titled “Anti-Constipation Composition,” which issued on July 2, 2002.

16. On information and belief, Sucampo AG owns United States Patent No. 8,071,613 (“the ‘613 patent”) titled “Anti-Constipation Composition,” which issued on December 6, 2011.

17. On information and belief, Sucampo AG owns United States Patent No. 7,795,312 (“the ‘312 patent”) titled “Method for Treating Abdominal Discomfort,” which issued on September 1, 2010.

18. On information and belief, Sucampo AG owns United States Patent No. 8,097,653 (“the ‘653 patent”) titled “Dosage Unit Comprising a Prostaglandin Analog for Treating Constipation,” which issued on January 17, 2012.

19. On information and belief, Sucampo AG owns United States Patent No. 8,389,542 (“the ‘542 patent”) titled .Dosage Unit Comprising a Prostaglandin Analog for Treating Constipation,” which issued on March 5, 2013.

20. On information and belief, Sucampo AG and R-Tech Ueno, Ltd. co-own United States Patent No. 8,026,393 (“the ‘393 patent”) titled “Soft-Gelatin Capsule Formulation,” which issued on September 27, 2011.

21. On information and belief, Sucampo AG and R-Tech Ueno, Ltd. co-own United States Patent No. 8,338,639 (“the ‘639 patent”) titled “Soft-Gelatin Capsule Formulation,” which issued on December 25, 2012.

22. On information and belief: Takeda Pharmaceutical Company Limited is an exclusive licensee to the patents-in-suit; Takeda Pharmaceuticals USA, Inc. is a sublicensee of Takeda Pharmaceutical Company Limited; and, Takeda Pharmaceuticals America, Inc. is a sublicensee of Takeda Pharmaceuticals USA, Inc.

23. Each of the patents-in-suit is listed in the U.S. FDA's Electronic Orange Book for one or both of the 8 mcg and 24 mcg lubiprostone capsules marketed in the United States under the trade name AMITIZA®.

24. DRL submitted Abbreviated New Drug Application No. 206994 ("ANDA 206996") to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) to obtain approval for the activities stated therein that required FDA approval. ANDA 206994 specifically seeks FDA approval to market products which are the subject of that ANDA prior to the expiration date listed in the Orange Book for the patents-in-suit.

25. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, DRL certified in ANDA 206994 that the claims of the patents-in-suit are invalid, unenforceable or will not be infringed by the manufacture, use, sale, offer to sell or importation into the United States of the products which are the subject of that ANDA.

### **THE ACTUAL CONTROVERSY**

26. Counterclaim Defendants filed the Complaint in this Court against DRL alleging that "By seeking approval of their ANDA No. 206994 to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of the ANDA Products prior to the expiration of the '016, '613, '312, '653, '542, '393, and '639 patents, Defendants have infringed those patents-in-suit under 35 U.S.C. § 271(e)(2)(A)."

27. In the complaint Counterclaim Defendants alleged that “DRL Inc. and DRL Ltd. are jointly and severally liable for infringement of the ‘016, ‘613, ‘312, ‘653, ‘542, ‘393, and ‘639 patents under 35 U.S.C. § 271(e)(2)(A).”

28. In the Complaint Counterclaim Defendants alleged that “If Defendants manufacture, use, offer to sell, or sell within the United States, or import into the United States, the ANDA Products prior to the expiration of the ‘016, ‘613, ‘312, ‘653, ‘542, ‘393, and ‘639 patents, Defendants will infringe one or more claims of these patents-in-suit under 35 U.S.C. § 271(a), (b) or (c).”

29. An actual and justiciable controversy exists regarding the ‘016, ‘613, ‘312, ‘653, ‘542, ‘393, and ‘639 patents, by virtue of the filing of the Complaint by Counterclaim Defendants. Thus, an actual controversy exists between DRL and Counterclaim Defendants as to whether any valid claim of the ‘016, ‘613, ‘312, ‘653, ‘542, ‘393, and ‘639 patents is or will be infringed by the commercial manufacture, use, offer to sell, sale or import of the products which are the subject of DRL’s ANDA 206994. DRL requires an immediate declaration of its rights vis-à-vis Counterclaim Defendants with respect to the products which are the subject of DRL’s ANDA 206994 and the ‘016, ‘613, ‘312, ‘653, ‘542, ‘393, and ‘639 patents.

### **FIRST COUNTERCLAIM**

30. DRL repeats and realleges the allegations contained in Paragraphs 1-29 of its Counterclaims as if fully set forth herein.

31. This counterclaim is for a declaration that the claims of United States Patents 6,414,016, 8,071,613, 7,795,312, 8,097,653, 8,389,542, 8,026,393, and 8,338,639 are invalid for failing to satisfy one or more conditions of patentability set forth in Title 35, United States Code,

including without limitation, §§ 101, 102, 103 and/or 112, and/or for non-statutory (obviousness-type) double patenting.

### **SECOND COUNTERCLAIM**

32. DRL repeats and realleges the allegations contained in Paragraphs 1-29 of its Counterclaims as if fully set forth herein.

33. This counterclaim is for a declaration that DRL has not infringed, induced infringement or contributed to the infringement, and DRL will not infringe, induce infringement or contribute to the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable claim of United States Patents 6,414,016, 8,071,613, 7,795,312, 8,097,653, 8,389,542, 8,026,393, and 8,338,639.

### **DRL'S REQUEST FOR RELIEF**

WHEREFORE, DRL respectfully requests that:

- (a) Judgment be entered that the Complaint against DRL is dismissed with prejudice and that Plaintiffs take nothing thereby;
- (b) Judgment be entered that the commercial manufacture, use, offer to sell, sale or import of the products which are the subject of DRL's ANDA 206994 do not and will not infringe any valid claim of United States Patents 6,414,016, 8,071,613, 7,795,312, 8,097,653, 8,389,542, 8,026,393, and 8,338,639;
- (c) Judgment be entered that the claims of United States Patents 6,414,016, 8,071,613, 7,795,312, 8,097,653, 8,389,542, 8,026,393, and 8,338,639 are invalid;
- (d) The Court permanently enjoin Plaintiffs or any of their assigns or successors from asserting that the commercial manufacture, use, offer to sell, sale or import of the products which are the subject of DRL's ANDA 206994 infringes or will infringe



any claim of United States Patents 6,414,016, 8,071,613, 7,795,312, 8,097,653, 8,389,542, 8,026,393, and 8,338,639;

- (e) This case be deemed an exceptional case within the meaning of 35 U.S.C. § 285;
- (f) DRL be awarded its attorney fees and costs of suit; and
- (g) The Court award DRL such other and further relief as this Court may deem necessary, just and proper.

Dated: January 26, 2015

Respectfully submitted,

By: s/ Louis H. Weinstein

Andrew J. Miller  
Louis H. Weinstein  
BUDD LARNER, P.C.  
150 John F. Kennedy Parkway  
Short Hills, NJ 07078  
Tel. 973-379-4800  
Fax: 973-379-7734  
[amiller@buddlerner.com](mailto:amiller@buddlerner.com)  
[lweinstein@buddlerner.com](mailto:lweinstein@buddlerner.com)

*Attorneys for Defendants  
Dr. Reddy's Laboratories, Inc. and  
Dr. Reddy's Laboratories, Ltd.*

**CERTIFICATE OF SERVICE**

I, Louis H. Weinstein, do hereby certify that on January 26, 2015, I caused a true and correct copy of Answer and Counterclaims of Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. to be served via ECF and e-mail on counsel for plaintiffs:

Charles M. Lizza  
William C. Baton  
Sarah A. Sullivan  
SAUL EWING LLP  
One Riverfront Plaza  
Newark, NJ 07102-5426  
[clizza@saul.com](mailto:clizza@saul.com)  
[wbaton@saul.com](mailto:wbaton@saul.com)  
[ssullivan@saul.com](mailto:ssullivan@saul.com)

s/ Louis H. Weinstein  
Louis H. Weinstein

1010827